K070565

MAY 1 8 2007

510(k) Summary
Smith and Nephew Cofield^2 Total Shoulder System

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-6055
Contact Person:	Marlon D. Ridley
Date Summary Prepared:	February 27, 2007
Trade or Proprietary Device Name:	Smith & Nephew Cofield^2 Total Shoulder System
Common or Usual Name:	Shoulder Joint Prosthesis
Classification Name:	Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis
Device Class:	Class II
Panel Code:	MBF Orthopaedics/ 87
Classification Name:	21 CFR 888.3670 - Shoulder joint metal/polymer/metal nonconstrained porous-coated uncemented prosthesis.

Device Intended Use
The Cofield^2 Total Shoulder System is indicated for the following:

Proximal Humeral Prosthesis

1. Complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma – three and four-part injuries in the Neer classification or head splitting, or head impression fractures).
2. Complex, chronic fractures or fracture-dislocations of the humeral head with malunion, non-union of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures.
3. Avascular necrosis with intact glenoid cartilage.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

Total Shoulder Arthroplasty
Severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures.

The Cofield^2 Total Shoulder System includes porous coated devices which are intended for use without bone cement, and are single use devices.

Device Description
The overall design, components, and materials of the Cofield^2 Total Shoulder System are substantially equivalent to the existing components of the Cofield^2 Total Shoulder System cleared under previous premarket notifications. The main difference between the subject components of the Cofield^2 Total Shoulder System and the currently marketed components is the intended use of the system without bone cement.

Substantially Equivalent
Cofield^2 Total Shoulder System - Smith & Nephew (K955767)
Cofield^2 Eccentric and Lateral Offset Humeral Heads - Smith & Nephew (K003566)
Global^{TM} Fx Porous-Coated Humeral Stem – Depuy Orthopaedics (K011099)
Bio-Modular® Shoulder System – Biomet Orthopedics (K030710)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc
% Mr. Marlon D. Ridley
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

MAY 18 2007

Re: K070565
Trade/Device Name: Smith & Nephew Cofield^2 Total Shoulder System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal unconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBF
Dated: February 26, 2007
Received: February 28, 2007

Dear Mr. Ridley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070565

Device Name: Smith & Nephew Cofield^2 Total Shoulder System

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070565